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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/384,248	02/06/95	ALIZON M	3495.0008-08

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EXAMINER	
PARKIN, J	
ART UNIT	**PAPER NUMBER**
1648	34

DATE MAILED: 10/26/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/384,248	Applicant(s) Alizon et al.
	Examiner Jeffrey S. Parkin, Ph.D.	Group Art Unit 1648

☒ Responsive to communication(s) filed on *3 Aug 1998*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *23 and 26-33* is/are pending in the application.

Of the above, claim(s) *26-31* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *23, 32, and 33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of the Response submitted 03 August, 1998. Claims 23, 32, and 33 are pending in the instant application. This application contains claims 26-31 drawn to an invention non-elected without traverse in Paper no. 3. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01).

35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 23, 32, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Applicants traversal can be summarized as follows: 1) The Examiner is applying improper legal criteria in making the rejection. 2) The specification provides literal support for the claimed method and teaches that the claimed λ-J19 restriction fragments encode HIV-1 antigens. Applicants' arguments have been thoroughly considered but are deemed to be nonpersuasive.

Concerning the first aspect of applicants' argument, the Examiner is quite aware of the legal criteria governing written description determinations. *Ralston Purina Company* v. *Far-Mar-Co., Inc.*, 227 U.S.P.Q. 177 (C.A.F.C. 1985). *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Blaser, Germscheid,* and *Worms,* 194 U.S.P.Q. 122 (C.C.P.A. 1977). *In re Driscoll,* 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter* v. *Hiraga,* 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). The courts have decided that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have decided that the specification must demonstrate that the inventor had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, nonetheless, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. Thus, the proper legal criteria have been applied in making this rejection.

Concerning the second aspect of applicants' arguments, the crux of the matter is whether the skilled artisan, upon perusal of the disclosure, would reasonably conclude that applicants were in possession of the claimed invention. The claimed invention is directed toward methods for the production of antibodies to HIV-1 antigens encoded by three λ-J19 restriction fragments (e.g., *Kpn*I (~6,100)/*Bgl*II (~9,150); *Kpn*I (~3,500)/*Bgl*II (~6,500); and, *Pst*I (~800)/*Kpn*I (3,500)). Contrary to applicants' assertions, the disclosure does not teach that the claimed restriction fragments encode the viral antigens of interest. While the disclosure provides a detailed restriction map, presumably of a proviral molecular clone (λ-J19), the coding potential of these restriction fragments is not readily manifest. As previously set forth, the disclosure does not provide the nucleotide sequences of any of these restriction

fragments, evidence that *bona fide* viral antigens were produced from said fragments, and evidence that antigen-specific antibodies were produced. While the disclosure (see page 13, last paragraph) vaguely refers to "immunogens and antigens" produced from these nucleic acids, it fails to provide any demonstrable evidence addressing the aforementioned caveats. Moreover, the disclosure fails to provide a suitable written description of method steps involving the production of an antigen from said restriction fragments, raising antibodies against said antigen, and recovering antigen-specific antibodies. Thus, upon perusal of the disclosure, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

As previously disclosed, this rejection is not based upon enablement considerations. The Examiner does not dispute the scientific findings that the skilled artisan, at the time of filing, provided with a restriction fragment capable of encoding a known antigen, could express and purify the antigen of interest and employ this protein to generate antigen-specific antibodies. This rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in possession of the claimed HIV-1 antigens and antibodies at the time of the filing date relied upon. The specification fails to provide any demonstrative evidence that applicants had generated expression vectors containing the claimed inserts, transfected suitable hosts, and produced suitable levels of recombinant HIV-1 proteins. Moreover, the disclosure fails to provide any evidence suggesting that these antigens were used to immunize animals and that HIV-1-specific antibodies were actually generated.

Finality of Office Action

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

5. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

7. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Chris Eisenschenk, J.D., Ph.D., can be reached at (703) 308-0452. Any inquiry of a general nature or

relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

22 October, 1998

FRANK C. EISENSCHENK
PRIMARY EXAMINER
GROUP 1800
10/23/98